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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,987	02/02/2005	Bernard Charles Sherman	2051-63	6965
23117	7590	10/22/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER ROGERS, JUNE MARIE	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/22/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/522,987	SHERMAN, BERNARD CHARLES	
	<b>Examiner</b>	<b>Art Unit</b>	
	Juné M. Rogers	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 page</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Priority***

Applicant's claim of priority to CA 2,395,931 filed August 7, 2002 is acknowledged. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Status of Claims***

Claims 1-14 are under consideration in this application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (WO 00/59475). Chen discloses compositions comprising (a) a hydrophobic therapeutic agent, having at least one ionizable functional group (b) a carrier, said carrier comprising (i) an ionizing agent; (ii) a surfactant and (iii) a triglyceride (claim 1, page 73). Chen discloses gabapentin is such a therapeutic agent (claims 4, 5, 10,). Chen discloses suitable ionizing agents to be sodium hydroxide, and salts of acids such as carbonic acid as well as sodium phosphate (page 14, lines 26-34 and page 15, lines 1-2). Chen teaches that sodium is the preferred cation when the base is a salt (page

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15, lines 2-5). Chen teaches that the compositions can contain other additives such as binders (page 52, line 27) and oral administration is the preferred (page 53 lines 8-9).

The prior art does not teach the specific binders recited in Applicant's claims 12 and 13; however the use of binders to formulate solid compositions is well known in the formulation art. In particular it is known in the art to use copolyvidone in gabapentin formulations as evidenced by Singer et al. (US 6,531, 509, col. 3, lines 23-30).

It is noted claims 10 and 11 are product by process claims; these claims are being treated by the Examiner as product claims because the process steps are not deemed to result in a modification of the product.

Therefore, it would have been obvious to one of ordinary skill, at the time of the invention to formulate a solid composition comprising gabapentin, a hydroxide or a salt of a weak acid and least one other excipient using traditional methods and materials known in the art because Chen teaches compositions comprising hydrophobic therapeutic agents, such as gabapentin; a carrier comprising, for example, sodium hydroxide and other excipients.

The prior art does not specifically teach the basic compound present in the composition in the amounts of Applicant's claims 7-9; however Chen discloses basic compounds, such as sodium hydroxide, are present in the composition. Accordingly, "[W] here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, Applicant has failed to demonstrate the criticality of the basic compound being present in the ranges recited in claims 7-9.

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**Conclusion**

No claims allowed.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juné M. Rogers whose telephone number is 571-270-3497. The examiner can normally be reached on M-T 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jmr

 10/20/07  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER